

November 10, 2015

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CERTIFIED MAIL-RETURN RECEIPT REQUESTED

Article number: 7015 1520 0003 0792 0084

Mr. Patrick J. Delaney
Administrative Director of Operations
Robert Wood Johnson University Hospital
110 Rehill Avenue
Somerville, NJ 08876

Re: **Notice of Violation**
RCRA § 3007 Information Request

Dear Mr. Delaney:

The U.S. Environmental Protection Agency (EPA) is charged with the protection of human health and the environment under the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. § 6901 et seq.

Pursuant to RCRA, as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), EPA promulgated rules, regulations, and standards governing the handling and management of hazardous waste as set forth in 40 Code of Federal Regulations (C.F.R.) Parts 260-272. For the purposes of this Notice of Violation and Information Request, the hazardous waste regulations governing the generation of hazardous waste were promulgated in 1980 and amended by HSWA in 1984.

The State of New Jersey is authorized by the EPA to conduct a hazardous waste program and to enforce RCRA under Section 3006 of RCRA, 42 U.S.C. § 6926. Notwithstanding, the EPA has retained its authority to enforce the hazardous waste rules and regulations in the State of New Jersey.

On or about May 14, 2015, a duly authorized representative of the EPA conducted a Compliance Evaluation Inspection (CEI) of Robert Wood Johnson University Hospital, Somerset located in Somerville, New Jersey, (the "facility") pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927. During the CEI, the EPA representative discussed the facility's generation and handling of wastes.

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The Notice of Violation (NOV) portion of this letter (Enclosure I) is issued pursuant to Section 3008 of the Solid Waste Disposal Act, as amended by RCRA and HSWA, 42 U.S.C. §§ 6901 and 6928. Issuance of this Notice of Violation and compliance with its terms does not preclude EPA from taking formal enforcement action against you and/or your company, including a monetary penalty, under Section 3008 of RCRA, 42 U.S.C. § 6928, or any other applicable regulation or statute.

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Pursuant to the provisions of Section 3007 of RCRA, 42 U.S.C. § 6927, EPA may require parties who handle or have handled hazardous waste to provide information relating to such wastes. Pursuant to the statutory provisions cited above, EPA hereby requires that you provide the information requested in Enclosure II, using the instructions and definitions included in Enclosure III. This information is necessary to determine the compliance status of Robert Wood Johnson University Hospital, Somerset.

Please provide the information requested no later than thirty (30) calendar days from receipt of this letter. Requests for additional time must be made within ten (10) calendar days of receipt of this letter and must be justified. A responsible official, officer, or agent of your facility, using the form in Enclosure IV to this letter, must sign the response. Failure to respond to this letter truthfully and accurately within the time provided may subject you to sanctions authorized by federal law, including but not limited to a potential enforcement action pursuant to Section 3008 of RCRA, 42 U.S.C. 6928. Please also note that all information you provide may be used in an administrative, civil judicial, or criminal action.

Your response to this letter must be mailed to the following address:

Ms. Meghan LaReau
Enforcement Officer
RCRA Compliance Branch
Division of Enforcement and Compliance Assistance
U.S. Environmental Protection Agency - Region 2
290 Broadway, 21st Floor
New York, New York 10007-1866

You may, if you so desire, assert a business confidentiality claim covering all or part of the information herein requested. The claim may be asserted by placing on (or attaching to) the information at the time it is submitted, a cover sheet, stamped or typed legend, or other suitable form of notice employing language such as "trade secret," "proprietary," or "confidential". The claim should set forth the information requested in 40 Code of Federal Regulations (hereinafter 40 "C.F.R.") Section 2.204(e)(4). Information covered by such a claim will be disclosed by EPA only to the extent permitted by, and by means of procedures set forth in, 40 C.F.R. Part 2. EPA will review the information to determine the extent of confidentiality of the information, and may, at its discretion, challenge the confidentiality claim pursuant to the procedures set forth at 40 C.F.R. Part 2. If no such claim accompanies the information when it is received by EPA, it may be made available to the public by EPA without further notice to you. If you contend that some or all of the submitted information is entitled to confidential treatment, specify which portions of the information you consider confidential. For each item or class of information that you identify as being subject to your claim, please answer the questions in Enclosure V, giving as much detail as possible. Please note that you bear the burden of substantiating your confidentiality claim.

Conclusory allegations will be given little or no weight in the determination.

Failure to respond in full to this requirement is a violation of RCRA Section 3007 and may result in federal enforcement action pursuant to Section 3008 of RCRA, 42 U.S.C. § 6928, including the assessment of a monetary penalty. Such penalties may be up to \$37,500 per day per violation.

This information request is not subject to the requirements of the Paperwork Reduction Act (PRA), as amended, 44 USC Part 3501 et. seq. If you have any questions regarding this matter, please contact Ms. Meghan La Reau, of my office, at (212) 637-4067 or lareau.meghan@epa.gov.

Sincerely yours,

Original signed by Leonard Voo

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Leonard Voo, Chief
RCRA Compliance Branch
Division of Enforcement and Compliance Assistance

Enclosures: Enclosure I - Notice of Violation
 Enclosure II - Information Request
 Enclosure III - Instructions & Definitions
 Enclosure IV - Certification of Answers
 Enclosure V – Substantiation of Confidential Business Information Claim

cc: Mike Hastry, Chief
 Bureau of Hazardous Waste Compliance and Enforcement
 Central Field Office, New Jersey Department of Environmental Protection
 300 Horizon Center- PO Box 407
 Trenton, NJ 08625-0407

Mary Jo Kelleher
Director of Risk Management
RWJ University Hospital
110 Rehill Avenue
Somerville, NJ 08876

ENCLOSURE I
NOTICE OF VIOLATION

Robert Wood Johnson University Hospital, Somerset

On or about May 14, 2015, a duly authorized representative of the EPA conducted a CEI of Robert Wood Johnson University Hospital, Somerset (the "Inspection") in order to determine the facility's compliance with state hazardous waste accumulation, storage and disposal regulations. As a result of the Inspection, the following specific violations were found:

General Requirements

1. 40 CFR § 262.34(d)(5)(iii), as incorporated by reference by NJAC 7:26G-6.1(a), requires that the generator must ensure that all employees are thoroughly familiar with proper waste handling and emergency procedures, relevant to their responsibilities during normal facility operations and emergencies.

According to training documents, the employee who signs the hazardous waste manifests had USDOT hazardous materials, transportation training and regulated medical waste training in June 2013. According to a sign in sheet for the training given in June 2013, other staff from Patient Support and Environmental Services received the training as well. However, no one from the Laboratory or Pharmacy Departments was listed as attending the training, and no other training records were available to review.

Container Storage Requirements

2. 40 CFR § 262.34(d)(4), as incorporated by reference by 40 CFR § 262.34(a)(2) and NJAC 7:26G-6.1(a), requires the generator to clearly mark on each container the date upon which each period of accumulation began.

At the time of the Inspection, hazardous waste containers, specifically 1 pint of silver nitrate and 1 liter Giemsa stain stock solution, in a flammable cabinet in the Hazardous Waste Storage Area had no accumulation start dates.

3. 40 CFR § 262.34(d)(4), as incorporated by reference by 40 CFR § 262.34(a)(3) and NJAC 7:26G-6.1(a), requires the generator to clearly mark on each container in storage areas with the words "Hazardous Waste".

At the time of the Inspection, at least one hazardous waste container, specifically 1 liter Giemsa stain stock solution, in a flammable cabinet in the Hazardous Waste Storage Area had no hazardous waste labels.

Accumulation Area Requirements

4. Pursuant to 40 CFR § 262.34(c)(1)(ii) as incorporated by reference by NJAC 7:26G-

6.1(a), the generator must clearly mark each container in accumulation areas with the words “Hazardous Waste” or with other words that identify the contents of the containers.

At the time of the Inspection, warfarin and nicotine patches being disposed in the Pharmacy Department were placed in a white polyethylene 5-gallon bucket. This bucket had no hazardous waste label. In Microbiology, a hazardous waste container of spent xylene was observed in a chemical cabinet and had no hazardous waste label.

Preparedness and Prevention

5. Pursuant to 40 CFR § 262.34(d)(4), as incorporated by reference by 40 CFR § 265.32(c) and NJAC 7:26G-6.1(a), all facilities must be equipped with fire extinguishers, fire control equipment, spill control equipment, and decontamination equipment.
6. Pursuant to 40 CFR § 262.34(d)(2), as incorporated by reference by 40 CFR § 265.174 and NJAC 7:26G-6.1(a), the generator must inspect, at least weekly, areas where containers are stored, looking for leaking containers and for deterioration of containers and the containment system caused by corrosion and other factors.
7. Pursuant to 40 CFR § 262.34(d)(5)(ii)(A), as incorporated by reference by NJAC 7:26G-6.1(a), the generator must post the names and telephone numbers of the emergency coordinators next to the telephone.
8. Pursuant to 40 CFR § 262.34(d)(5)(ii)(B), as incorporated by reference by NJAC 7:26G-6.1(a), the generator must post the location of fire extinguishers and spill control material and, if present, fire alarm, next to the telephone.

Based on the hazardous waste management procedure in the Laboratory, the hallway hazardous waste storage closet is a permanent hazardous waste storage area. At the time of the Inspection, there were hazardous waste containers, specifically a 5-gallon container of waste xylene/alcohol, and a full 5-gallon container of xylene/alcohol waste. One “empty” container of xylene/alcohol waste was observed but had some liquid still in the container stored in the closet. A phone was observed in the closet but no emergency postings. No spill kit or fire extinguisher was observed and the room is not inspected weekly.

Universal Waste

9. Pursuant to 40 CFR § 273.14 (a), universal waste batteries, or a container in which batteries are contained, must be labeled or marked clearly with any one of the following phrases: “Universal Waste – Battery(ies),” or “Waste Battery(ies),” or “Used Battery(ies).”

At the time of the Inspection, the following waste was observed: A 55-gallon drum of lead-acid batteries closed with no proper Universal Waste label and two 5-gallon buckets of nickel cadmium and lithium ion batteries all closed with no proper Universal Waste labels.

ENCLOSURE II
INFORMATION REQUEST

Robert Wood Johnson University Hospital, Somerset

On or about May 14, 2015, a duly authorized representative of the EPA conducted a CEI of Robert Wood Johnson University Hospital, Somerset. Based on a review of the information obtained during the CEI, EPA has determined that the following information is required to evaluate the compliance of the facility:

The relevant time period for every question is May 14, 2012 through the date of receipt of this letter, unless otherwise specified.

1. In regards to the violations cited in the above Notice of Violation, please provide the following:
 - a. A description of the actions taken to correct each of the violations cited, if not already provided in an earlier submission;
 - b. Documentation verifying that the violations have been corrected, including photographs, where applicable; and,
 - c. An account and description of changes in facility management practices sufficient to preclude a recurrence of the violations.
2. If not already provided, please provide the following information on hazardous waste management and training:
 - a. Please list each position at the facility related to hazardous waste management. This includes each position where hazardous waste may be handled, transported between rooms, etc. Please include the job title and description of duties, and whether the position is full or part time. Please include all personnel in the Pharmacy and Laboratory Departments.
 - b. For each person filling each position listed above, please state when that person began employment.
 - c. For each person filling each position listed in above, please list all training completed including the dates training was received and a detailed description of the content of the training.
3. Please describe how spent lead aprons and spent x-ray films were managed prior to the Robert Wood Johnson merger in 2014. Include how the waste was classified (i.e., as solid and/or hazardous waste), whether the facility or any third party acting on behalf of the facility disposed or arranged for the disposal of the waste, the name and address of the third party, and provide all supporting documentation such as contracts, bills of lading and/or hazardous waste manifests.

4. When submitting your response, attach to the Certification of Answers to Request for Information (Enclosure IV, below) a list of persons by name, position or title, and company who prepared or assisted in the preparation of the responses to this information request.

ENCLOSURE III
INSTRUCTIONS AND DEFINITIONS

Robert Wood Johnson University Hospital, Somerset

In responding to this Request for Information, apply the following instructions and definitions:

1. The signatory should be an officer or agent who is authorized to respond on behalf of Robert Wood Johnson University Hospital, Somerset. The signatory must sign the attached Certification of Answers (Enclosure IV) and return it with the response to this Request for Information.
2. A complete response must be made to each individual question in this Information Request. Identify each answer with the corresponding number listed in Enclosure II.
3. In preparing your response to each question, consult with all present and former employees and agents of the facility who may be familiar with the matter to which the question pertains.
4. In answering each question, identify all contributing sources of information.
5. If you are unable to answer a question in a detailed and complete manner or if you are unable to provide any of the information or documents requested, indicate the reason for your inability to do so. If you have reason to believe that there is an individual who may be able to provide more detail or documentation in response to any question, state that person's name and last known address and phone number and the reasons for your belief.
6. If you cannot provide a precise answer to any question, please approximate and state the reason for your inability to be specific.
7. For each document produced in response to this Request for Information, indicate on the document or in some other reasonable manner, the number or letter of the question to which it applies.
8. If anything is deleted or redacted from a document produced in response to this Request for Information, state the reason for and the subject matter of the deletion.
9. If a document is requested but is not available, state the reason for its unavailability. In addition, identify any such document by author, date, subject matter, number of pages, and all recipients and their addresses.
10. The facility, for the purposes of this Notice of Violation and Request for Information, are all areas of Robert Wood Johnson University Hospital, Somerset located on 110 Rehill Avenue in Somerville, New Jersey.
11. A *hazardous waste generator* is defined, for the purposes of this Request for Information,

as any person (which includes this facility) whose act or process produces hazardous waste or whose act first causes a hazardous waste to become subject to regulation.

12. *Hazardous waste* is defined, for the purposes of this Request for Information, as it is defined in Section 1004(5) of RCRA, as amended, 42 USC Part 6903(5).
13. *Universal waste* means any of the following hazardous waste that are subject to the universal waste requirements of Part 273: batteries as described in §273.2, pesticides as described in §273.3, thermostats as described in §273.4, and lamps as described in §273.5.
14. *Manage* is defined, for the purposes of this Request for Information, as: to market, generate, treat, store, dispose, or otherwise handle.

**ENCLOSURE IV
CERTIFICATION OF ANSWERS**

Robert Wood Johnson University Hospital, Somerset

CERTIFICATION OF ANSWERS TO REQUEST FOR INFORMATION

I certify under penalty of law that I have personally examined and am familiar with the information submitted in response to EPA's Request for Information, and all documents submitted herewith; that the submitted information is true, accurate, and complete; and that all documents submitted herewith are complete and authentic, unless otherwise indicated. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment.

Name (print or type)

SIGNATURE

DATE

TITLE

ENCLOSURE V
SUBSTANTIATION OF CONFIDENTIAL BUSINESS INFORMATION CLAIM

Robert Wood Johnson University Hospital, Somerset

1. For what period of time do you request that the information be maintained as confidential, *e.g.*, until a certain date, until the occurrence of a specified event, or permanently? If the occurrence of a specific event will eliminate the need for confidentiality, please specify that event.
2. Information submitted to EPA becomes stale over time. Why should the information you claim as confidential be protected for the time period specified in your answer to Question 1, immediately above?
3. What measures have you taken to protect the information claimed as confidential and to guard against undesired disclosure? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose the information further? If so, why should the information still be considered confidential?
4. Is the information contained in any publicly available material such as the Internet, publicly available databases, promotional publications, annual reports, or articles? Is there any means by which a member of the public could obtain access to the information? Is the information of a kind that you would customarily not release to the public?
5. Has EPA or any other governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.
6. For each category of information claimed as confidential, explain with specificity why release of the information is likely to result in substantial harmful effects on the business or to its competitive position. Explain the specific nature of those harmful effects; why they should be viewed as substantial, and the causal relationship between disclosure and such harmful effects. How could your competitors make use of this information to your detriment?
7. Do you assert that the information is submitted on a voluntary or a mandatory basis? Please explain the reason for your assertion. If the business asserts that the information is voluntarily submitted information, whether and why disclosure of the information would tend to lessen the availability to EPA of similar information in the future.
8. Any other issue you deem relevant.